

**I. Preliminary Remarks**

This response is timely filed with a one month extension. Should the Patent Office determine that additional fees are required for consideration of this response, permission is hereby granted to charge such fees to Deposit Account No. 033975. Any overpayments should be credited to the same account.

**II. Restriction**

Citing 35 U.S.C. § 121, the examiner alleged that claims 1-34 are directed to the following five distinct inventions:

- Group I.* Claims 1-18 (claims directed to a method for treatment of cancer with a p75 gene);
- Group II.* Claim 20 (claims directed to a combination method for treatment of cancer with a p75 gene and a RNA binding protein);
- Group III.* Claim 21 (claims directed to a combination method for treatment of cancer with a p75 gene and an agent that regulates cell nutrients and or cytokines associated with p75 mRNA stability);
- Group IV.* Claim 23 (claims directed to a method for treatment of cancer with an RNA binding protein);
- Group V.* Claim 24 (claims directed to a method for treatment of cancer with an agent that regulates cell nutrients and or cytokines associated with p75 mRNA stability);
- Group VI.* Claims 25-27 and 30 (claims directed to a method for diagnosing prostate cancer involving measuring p75 mRNA levels);
- Group VII.* Claim 31 (claims directed to a method for treatment of cancer with an agent that promotes expression of an endogenous p75 gene); or
- Group VIII.* Claims 32-34 (claims directed to a method for treatment of cancer with the p75 protein).

Prior to election, the applicants wish to point out to the examiner that they believe claims 19, 22, 28, and 29 have not been placed in any restriction group. Claim 19 is directed to the method of claim 1, further comprising administering to the subject a p75<sup>NTR</sup> mRNA stabilizing agent. The applicants submit that both the p75<sup>NTR</sup> gene product and a RNA

stabilizing are part of the component used in the method steps of Group I. Accordingly, claim 19 should be placed in Group I.

Similarly, claim 28 is directed to a method of reducing or preventing prostate tumor metastasis in a subject in need thereof comprising administering to the subject a p75<sup>NTR</sup> gene or a fragment thereof in an amount effective to prevent or reduce tumor metastasis. The applicants respectfully submit claim 28 is directed to using p75 gene to treat prostate tumors, which is a direct consequence of cancerous cells. Accordingly, the method of claim 28 appears to be a method of treating cancer using p75 as recited in the method steps of Group I. Thus, claim 28 should be placed in Group I as well. **The undersigned respectfully requests that the examiner address this issue in the next Communication from the Patent Office.**

### **III. Election**

The applicants hereby elect Group I, which includes claims 1-18 directed a method for treatment of cancer with a p75 gene, with traverse.

### **IV. Traversal Arguments—Restriction of Claims 1-34 are Improper**

The applicants request examination of Groups I, II, III, VI, and VIII together, in view of the fact that the inventions cited by the examiner as representative of Groups I, II, III, VI, and VIII are related inventions and examination of all claims combining these groups (including claims 19 and 28 as discussed above) would not constitute an undue burden on the Patent Office.

Specifically, the applicants respectfully submit the examiner has failed to place claim 19 into a particular grouping yet, this claim is a linking claim where both the p75 gene is combined with the mRNA stabilizing agent. This combination RNA agent and p75 gene can comprise an RNA-binding protein (claim 20), and these RNA proteins are capable of regulating cell nutrients and/or cytokines (claim 21). In each of these groups, p75 gene is present and being used in the combination cocktails, which can be used in the methods for treating cancer with p75 as presented in Group I.

With regard to Group VI claims, the method of diagnosing prostate cancer involves measuring p75 mRNA levels. The level of p75 mRNA would also be measured in claim 2, which is directed to administering an amount sufficient to maintain a level of p75 mRNA to compensate for the loss of p75 mRNA levels due to a loss from prostate cancer. Both

processes would involve measuring p75 mRNA levels not only to diagnose the prostate cancer, for example, but also to monitor and treat the prostate cancer as claimed in Group I. With regard to Group VIII, the protein product of the p75 gene is being used to treat the tumors by the method claimed in Group I. The p75 protein product of Group VIII is generated by the p75 gene which is administered as claimed in Group I. Therefore, any search designed to identify documents relevant to the patentability of the claimed method in Group I will employ the same or similar search terms and techniques as in Groups II, III, VI, and VIII.

Accordingly, the applicants submit that the recently issued restriction is unnecessary and improper. Should the present restriction be maintained, the applicants hereby notify the examiner of their intention to request rejoinder upon a notice of allowance of the claims of Group I.

**V. Conclusion**

In view of the foregoing, the applicant submits that they have fully and properly responded to the outstanding restriction requirement. Should the examiner have any questions or comments regarding this response or the application, the examiner is urged to contact the undersigned at the number indicated.

Respectfully submitted,

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